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Evelina Smith

/Evelina Smith/

April 27, 2010

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Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : GOYVAERTS, et al. Confirmation No.: 9953
Serial No. : 10/596,732
Filed : June 22, 2006
Title : PROCESS FOR THE PREPARATION OF (3R,3AS,6AR)-HEXAHYDROFURO [2,3-B] FURAN-3-YL (1S,2R)-3-[(4-AMINOPHENYL) SULFONYL] (ISOBUTYL) AMINO]-1-BENZYL-2-HYDROXYPROPYLCARBAMATE
Art Unit : 1625
Examiner : Patricia L. Morris

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATIONS FOR PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. 1.705(b) WITHIN THREE MONTHS OF RECEIPT OF THE
NOTICE OF ALLOWANCE

Dear Sir:

Responsive to the Determination of Patent Term Adjustment posted on the Patent Application Information Retrieval System (PAIR) and provided with the Notice of Allowance (mailed January 28, 2010), and in light of the recent ruling in *Wyeth v. Dudas*, No. 2009-1120, slip op. (Court of Appeals for the Federal Circuit) the Applicants submit this Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705. As stated in 37 C.F.R. 1.705(b):

Any request for reconsideration of the patent term adjustment indicated in the notice of allowance, except as provided in paragraph (d) of this section, and any request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) must be by way of an application for patent term adjustment. An application for patent term adjustment under this section must be filed no later than the payment

of the issue fee but may not be filed earlier than the date of mailing of the notice of allowance.

This request is being submitted before payment of the issue fee (due April 28, 2010), and complies with the relevant deadline specified in 37 C.F.R. 1.705. Thus, Applicants contend this request is timely.

1. Payment of fee under §1.18(e) or §1.18(f)

Applicants hereby authorizes the Patent Office to charge the fee set forth in §1.18(e) or 1.18(f) and any other fees that may be due to Deposit Account 10-0750/TIP0056USPCT/AGK.

2. Statement of Facts

Applicants respectfully request that at least an additional 162 days of Patent Term Adjustment be added to the 630 days of additional patent term for Patent Office delay already calculated on PAIR, resulting in a total Patent Term Adjustment of 792 days.

A. “USPTO “A Delay” Calculation

The USPTO’s determination of the delay in prosecution, which, for purposes of this request and in keeping with the explanation provided in *Wyeth*, Applicants will refer to as the “A delay. The “A delay” patent term adjustment was determined to be to 630 days in the Notice of Allowance mailed January 28, 2010 at page 3.

B. “B Delay” Calculation

“B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency.

37 CFR § 1.702 (b), states:

Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C.

371(b) or (f) in an international application, but not including: (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b); (2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a); (3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181; (4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or (5) Any delay in the processing of the application by the Office that was requested by the applicant.

When calculating "B Delay", application pendency is measured from the date that is three years after the date that the application was filed. National Stage under 35 U.S.C. 371(c) for this application commenced on June 22, 2006, and the date that is "three years later" is June 22, 2009.

The B period does not include, however, any applicant delays, of the following:

- (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b);
- (2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a);
- (3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;
- (4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or
- (5) Any delay in the processing of the application by the Office that was requested by the applicant.

In the present application, a Request for Continued Examination was filed on December 2, 2009. Thus, the "B" delay for the instant application is 162 days, which is the period running from June 22, 2009 (the date that is three years after commencement of National Stage) until the filing of the Request for Continued Examination on December 2, 2009.

The Patent Office has **not** included in the Patent Term Adjustment the days related to the "B delay," which are the days delay resulting from an application pending longer than three years. According to 37 C.F.R. 1.703(b):

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage

commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued...

The *Wyeth* decision states that the Federal Circuit affirmed the District Court's decision which held that "the 'A period' and 'B period' overlap only if they occur on the same calendar day or days" (D.D.C. Sept 30, 2008, No. 07-1492, slip op. at 8).

Thus, according to the *Wyeth* decision, Applicants are entitled to both the "A delay" of 630 days and the "B delay" of 162 days minus any overlap that occurs on the same calendar days.

According to the PAIR information, and the above dates, there is not an overlap of calendar days between the "A delay" (162 days) and the "B delay" (630 days).

The "A" delay of 630 days occurred between August 23, 2007 (the date that is fourteen months after June 23, 2006, the date the application fulfilled the requirements of 35 USC 371) and May 14, 2009, the mailing date of the first substantive office action.

The "B" delay of 162 days occurred between from June 22, 2009 (the date that is three years after commencement of National Stage on June 22, 2006) until the filing of the Request for Continued Examination on December 2, 2009.

Thus, there is no overlap of the "A" delay (running from August 23, 2007 to May 14, 2009) with the "B" day (running from June 22, 2009 to December 2, 2009).

Accordingly, the Patent Term Adjustment for this case should be 162 days of "A" delay, plus 630 days of "B" delay, which equals 792 days.

3. Other Circumstances

As required under 37 C.F.R. §1.705(b)(2)(iii) and (iv)(B), Applicant states:

(1) this application is not subject to a Terminal Disclaimer; and

(2) confirms that except for the Applicant's delay periods as acknowledged by the Patent Office in its calculation of the "A" delay, there were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

4. Conclusion

In light of the foregoing, the Applicants respectfully request that at least an additional 162 days of Patent Term Adjustment to be added to the 630 days of patent term adjusted already calculated on PAIR, resulting in a total Patent Term Adjustment of 792 days.

If a telephone conference would expedite the prosecution of this Request for Reconsideration of Patent Term Adjustment, please contact the undersigned agent as indicated below.

Respectfully submitted,

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